

**Statutory Instruments.**

**S.I. No. 393 of 2006**

**European Communities (Authorization, Placing on the Market, Use and  
Control of Biocidal Products) (Amendment) Regulations 2006**

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**S.I. No. 393 of 2006**

**European Communities (Authorization, Placing on the Market, Use and Control of Biocidal Products)  
(Amendment) Regulations 2006**

I, Mary Coughlan, Minister for Agriculture and Food, in exercise of the powers conferred on me by section 3 of the European Communities Act, 1972 (No. 27 of 1972), for the purpose of giving further effect to Directive No 98/8/EC of the European Parliament and of the Council of 16 February 1998<sup>1</sup>, and to give effect to Commission Directive 2006/50/EC of 29 May 2006<sup>2</sup>, hereby make the following Regulations:

**Citation**

- 1 These Regulations may be cited as the European Communities (Authorization, Placing on the Market, Use and Control of Biocidal Products) (Amendment) Regulations 2006.
- 2 The European Communities (Authorization, Placing on the Market, Use and Control of Biocidal Products) Regulations 2001 (S.I. No. 625 of 2001) are amended in Regulation 2(1) by inserting the following: -

“ ‘PCS number’ means the number allocated to a biocidal product on its inclusion in the register of biocidal products;

“premises” includes land (including land under water) with or without buildings, an establishment, a vehicle (including a boat, ship, hovercraft, aircraft or offshore installation (being an offshore installation within the meaning of the Safety, Health and Welfare (Offshore Installations) Act 1987 (No. 18 of 1987)), railway wagon, container or other thing used in connection with, or ancillary to, a thing aforesaid;

‘professional use’ in relation to a biocidal product means use for commercial purposes, for trade or business, or in the maintenance of commercial property, sports facilities, amenity areas, roads, waterways, or railways;

‘register of biocidal products’ means a list established under Regulation 29 (3);”

- 3 The European Communities (Authorization, Placing on the Market, Use and Control of Biocidal Products) Regulations 2001 (S.I. No. 625 of 2001) are amended by substituting for Regulation 9 the following: -

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<sup>1</sup> O.J. No. L123 24/04/1998 p.1

<sup>2</sup> O.J. No. L142 30/05/2006 p. 6

**“Placing on the market and use of biocidal products**

- 9 (1) Subject to paragraphs (6) and (7), the placing on the market and use of a biocidal product after the first day of April 2002 is hereby prohibited:
- (a) unless it has been notified, authorized or registered in accordance with these Regulations and is placed on the market and used in compliance with any conditions or restrictions associated with such notification, authorization or registration;
  - (b) unless it is a commodity substance included in Annex IB; or
  - (c) where such placing on the market and use has been provisionally prohibited pursuant to the provisions of Regulation 22.
- (2) Subject to paragraphs (6) and (7), biocidal products shall be used:
- (a) in a proper manner involving the rational combination of physical, biological, chemical or other measures as appropriate, whereby the use of the biocidal product is limited to the minimum necessary;
  - (b) in accordance with the conditions of use established pursuant to Regulation 10 and specified on the label of the biocidal product; and
  - (c) in accordance with the terms of any restriction established pursuant to Regulation 22.
- (3) End users of biocidal products for professional use shall maintain at least the following records that on request made shall be produced for inspection by an authorized officer
- 
- (a) the name and address of the supplier of product and for each such product,
    - the brand name of each product received,
    - the PCS number of each product received,
    - the pack size or sizes and quantities of each product received,
    - the quantity of each product received (kilograms or litres),
  - (b) for each product used or applied,
    - the brand name of each product,
    - the PCS number of each product,
    - the date or dates of use of each product,
    - the purpose for which each product was used,
    - the quantity of each product used (kilograms or litres), and
  - (c) for each product returned and for disposals,

- the name of the company to which returned or the name of the disposal company or organization,
  - the brand name of each product disposed of or returned,
  - the PCS number of each product disposed of or returned,
  - the date of return or disposal of each product,
  - the quantity of each product disposed of or returned.
- (4) Notwithstanding the requirements of paragraph (3), end users of biocidal products intended for professional use, may on application made be exempted from some or all of the requirements specified in that paragraphs, where the Minister is satisfied that the quantities used are very small and the periods for which biocidal products are stored are very brief.
- (5) Biocidal products shall be classified, packaged and labelled in accordance with the provisions of these Regulations.
- (6) The provisions of paragraphs (1) and (2) shall not apply to experimental biocidal products intended for use in process-oriented research and development or scientific research and development in accordance with the provisions of Regulation 15, 16 and 17.
- (7) The provisions of subparagraph (2) (b) shall not apply to biocidal products placed on the market and used in accordance with the transitional arrangements provided for in paragraphs (1), (2), (3) and (4) of Regulation 14.
- (8) Where biocidal products are used in the workplace, such use shall be in accordance with the requirements of legislation in place for the protection of workers.
- (9) Notwithstanding non-compliance with the provisions of this Regulation, an authorized officer acting on behalf of the Minister, where there is no apparent risk to man or to the environment through the placing on the market or use of a non-compliant biocidal product, may, by a notice in writing given to the owner or person in apparent charge or control, permit the controlled placing on the market or use of existing stocks of the biocidal product subject to specified conditions.”

4 The European Communities (Authorization, Placing on the Market, Use and Control of Biocidal Products) Regulations 2001 (S.I. No. 625 of 2001) are amended by substituting for paragraphs (4) and (5) of Regulation 37, the following:-

“(4) Where a sample is taken pursuant to this Regulation, the authorised officer concerned shall:

- (a) either:
- (i) divide the sample into two or more parts, each of which he or she shall seal and mark, or

- (ii) where the procedure specified in subparagraph (i) would or could result in the division of individual units, identify 2 or more units of the batch of material to be sampled, or 2 or more packages or containers containing material from the batch of material to be sampled, as appropriate, each unit, package or container of which shall constitute a part which he or she shall seal and mark;
  - (b) give, deliver to, or send by registered post one part thereof to a designated analyst for analysis in accordance with paragraph (5);
  - (c) leave with, deliver to, or send by registered post to the defendant or prospective defendant or his or her agent, a second part thereof;
  - (d) where there is more than one defendant or prospective defendant, leave with, deliver to, or send by registered post to such defendant or prospective defendant or agent of such defendant or prospective defendant, one or more further parts thereof.
- (5) Where a designated analyst receives a sample from an authorized officer in pursuance of these Regulations he or she shall make analyses thereof using appropriate analytical methods.”

5 The European Communities (Authorization, Placing on the Market, Use and Control of Biocidal Products) Regulations 2001 (S.I. No. 625 of 2001) are amended by substituting for Regulation 39 the following: -

**“General offences**

- 39 (1) A person who contravenes Regulation 6 or 9, paragraph (1) of Regulation 15, paragraph (1) of Regulation 16 or Regulation 22 shall be guilty of an offence and shall be liable on summary conviction to a fine not exceeding €5,000 to imprisonment for a term not exceeding six months, or to both.
- (2) If any person:
- (a) tampers with an active substance or a biocidal product so as to procure that any sample of it taken pursuant to Regulation 37 does not correctly represent the active substance or the biocidal product; or
  - (b) tampers with any controlled product, article, commodity, soil, effluent, or thing treated with or contaminated with a biocidal product so as to procure that any sample of it taken pursuant to Regulation 37 does not correctly represent the controlled product, article, commodity, soil, effluent, or thing; or
  - (c) tampers or interferes with any sample taken pursuant to these Regulations,
- he or she shall be guilty of an offence and shall be liable on summary conviction to a fine not exceeding €5,000 or to imprisonment for a term not exceeding six months or to both.

(3) A person who:

- (a) fails to comply with the requirements of Regulation 4 or 7, paragraphs (1), (2), (3), (4) or (5) of Regulation 14, paragraphs (2) or (3) of Regulation 15, paragraph (2), (3), (4) or (5) of Regulation 16, paragraphs (2), (4) or (5) of Regulation 17, paragraph (1) of Regulation 19, Regulation 21, paragraph (4) of Regulation 26, paragraphs (2) or (5) of Regulation 28, Regulation 30, 31, 32, 33, 34 or 36, paragraphs (2) or (3) of Regulation 37 or paragraph (3) of Regulation 38;
- (b) obstructs or interferes with an authorised officer in the course of exercising a power conferred on him or her by Regulation 37 or 38 or paragraph (9) of Regulation 42; or
- (c) in the context of Regulation 4 or 7, paragraph (1) of Regulation 11, paragraphs (2), (3), (4) or (5) of Regulation 14, paragraphs (2) or (3) of Regulation 15, paragraphs (2), (3), (4), or (5) of Regulation 16, paragraph (1) of Regulation 17, paragraph (2) of Regulation 19, paragraph (3) of Regulation 20, Regulation 21, paragraph (1) of Regulation 26, paragraph (3) of Regulation 28, or Regulation 34 or 36 submits false or misleading information, or who gives false information when requested to provide information under paragraphs (2) or (3) of Regulation 37 or paragraph (9) of Regulation 42;

shall be guilty of an offence and shall be liable on summary conviction to a fine not exceeding €5,000, to imprisonment for a term not exceeding six months, or to both.

- (4) Where an offence under these Regulations has been committed by a body corporate and is proved to have been so committed with the consent, or connivance of, or to be attributable to any neglect on the part of any director, manager, secretary or other officer of the body corporate, or a person who was purporting to act in any such capacity, that person as well as the body corporate, shall be guilty of an offence and shall be liable to be proceeded against as if he or she were guilty of the first mentioned offence.”

- 6 The European Communities (Authorization, Placing on the Market, Use and Control of Biocidal Products) Regulations 2001 (S.I. No. 625 of 2001) are amended by deletion of Regulation 41.
- 7 The European Communities (Authorization, Placing on the Market, Use and Control of Biocidal Products) Regulations 2001 (S.I. No. 625 of 2001) are amended by substituting for Part 8 of the First Schedule, Part 8 as set out in the First Schedule to these Regulations.
- 8 The European Communities (Authorization, Placing on the Market, Use and Control of Biocidal Products) Regulations 2001 (S.I. No. 625 of 2001) are amended by substituting for Part 9 of the First Schedule, Part 9 as set out in the Second Schedule to these Regulations.

- 10 The European Communities (Authorization, Placing on the Market, Use and Control of Biocidal Products) Regulations 2001 (S.I. No. 625 of 2001) are amended by deletion of the Fifth Schedule.

## **FIRST SCHEDULE**

### **Part 8**

#### **Annex IVA**

#### **DATA SET FOR ACTIVE SUBSTANCES**

#### **MICRO-ORGANISMS INCLUDING VIRUSES AND FUNGI**

- 1 For the purposes of this Annex, the term micro-organisms shall be understood as including also viruses and fungi. Dossiers on active micro-organisms shall address at least all the points listed under “Dossier requirements” below. For all micro-organisms subject to an application for inclusion into Annex I or IA, all available relevant knowledge and information in literature must be provided. The information related to the identification and characterisation of a micro-organism including mode of action is particularly important and must be entered in sections I to IV and provides the basis for an assessment of potential impacts on human health and of environmental effects.
- 2 Where information is not necessary owing to the nature of the micro-organism the provisions of Regulation 4 (6) shall apply.
- 3 A dossier within the meaning of Regulation 7 shall be prepared on strain level of the micro-organism unless information is submitted that shows that the species is known to be sufficiently homogeneous regarding all characteristics, or the applicant provides other arguments in accordance with the provisions of Regulation 4 (6).
- 4 Where the micro-organism has been genetically modified within the meaning of Regulation 2, a copy of the evaluation of the data concerning the assessment of the risks to the environment as established in accordance Regulation 11 (5) and (6), shall also be submitted.
5. If the biocidal product action is known to be partly or entirely due to the effect of a toxin/metabolite, or if significant residues of toxins/metabolites are to be expected not related to the effect of the active micro-organism, a dossier for the toxin/metabolite shall be submitted in accordance with the requirements of Annexes IIA and, where specified, the relevant parts of Annex IIIA.

#### **Dossier requirements**

#### **SECTIONS**

- I Identity of the micro-organism
- II Biological properties of the micro-organism
- III Further information on the micro-organism
- IV Analytical methods



**First schedule      Part 8      Annex IVA      Data set for active substances**  
**Micro-organisms including viruses and fungi**

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- V      Effects on human health
- VI     Residues in or on treated materials, food and feed
- VII    Fate and behaviour in the environment
- VIII   Effects on non-target organisms
- IX     Classification and labelling
- X      Summary and evaluation of sections I to IX including conclusions of the risk assessment and recommendations

The following data will be required to support submissions on the above points.

**I      IDENTITY OF THE MICRO-ORGANISM**

- 1.1    Applicant
- 1.2    Manufacturer
- 1.3    Name and species description, strain characterisation
  - 1.3.1   Common name of the micro-organism (including alternative and superseded names)
  - 1.3.2   Taxonomic name and strain indicating whether it is a stock variant, a mutant strain or a genetically modified organism (GMO); for viruses, taxonomic designation of the agent, serotype, strain or mutant
  - 1.3.3   Collection and culture reference number where the culture is deposited
  - 1.3.4   Methods, procedures and criteria used to establish the presence and identity of the micro-organism (*e.g.* morphology, biochemistry, serology, *etc.*)
- 1.4    Specification of the material used for manufacturing of formulated products
  - 1.4.1   Content of the micro-organism
  - 1.4.2   Identity and content of impurities, additives, contaminating micro-organisms
  - 1.4.3   Analytical profile of batches

**II     BIOLOGICAL PROPERTIES OF THE MICRO-ORGANISM**

- 2.1    History of the micro-organism and its uses. Natural occurrence and geographical distribution
  - 2.1.1   Historical background

- 2.1.2    Origin and natural occurrence
- 2.2      Information on target organism(s)
  - 2.2.1    Description of the target organism(s)
  - 2.2.2    Mode of action
- 2.3      Host specificity range and effects on species other than the target organism
- 2.4      Development stages/life cycle of the micro-organism
- 2.5      Infectiveness, dispersal and colonisation ability
- 2.6      Relationships to known plant or animal or human pathogens
- 2.7      Genetic stability and factors affecting it
- 2.8      Information on the production of metabolites (especially toxins)
- 2.9      Antibiotics and other anti-microbial agents
- 2.10     Robustness to environmental factors
- 2.11     Effects on materials, substances and products
- 
- III      FURTHER INFORMATION ON THE MICRO-ORGANISM
  - 3.1      Function
  - 3.2      Field of use envisaged
  - 3.3      Product type(s) and category of users for which the micro-organism should be listed in Annex I, IA or IB
  - 3.4      Method of production and quality control
  - 3.5      Information on the occurrence or possible occurrence of the development of resistance of the target organism(s)
  - 3.6      Methods to prevent loss of virulence of seed stock of the micro-organism
  - 3.7      Recommended methods and precautions concerning handling, storage, transport or fire
  - 3.8      Procedures for destruction or decontamination
  - 3.9      Measures in case of an accident
  - 3.10     Procedures for waste management

- 3.11      Monitoring plan to be used for the active micro-organism including handling, storage, transport and use

#### IV      ANALYTICAL METHODS

- 4.1      Methods for the analysis of the micro-organism as manufactured
- 4.2      Methods to determine and quantify residues (viable or non-viable)

#### V      EFFECTS ON HUMAN HEALTH

##### **TIER I**

- 5.1      Basic information
- 5.1.1      Medical data
- 5.1.2      Medical surveillance on manufacturing plant personnel
- 5.1.3      Sensitisation/allergenicity observations
- 5.1.4      Direct observation, *e.g.* clinical cases
- 5.2      Basic studies
- 5.2.1      Sensitisation
- 5.2.2      Acute toxicity, pathogenicity, and infectiveness
- 5.2.2.1      Acute oral toxicity, pathogenicity and infectiveness
- 5.2.2.2      Acute inhalation toxicity, pathogenicity and infectiveness
- 5.2.2.3      Intraperitoneal/subcutaneous single dose
- 5.2.3      *In vitro* genotoxicity testing
- 5.2.4      Cell culture study
- 5.2.5      Information on short-term toxicity and pathogenicity
- 5.2.5.1      Health effects after repeated inhalatory exposure
- 5.2.6      Proposed treatment: first aid measures, medical treatment
- 5.2.7      Any pathogenicity and infectiveness to humans and other mammals under conditions of immunosuppression

**END OF TIER I**  
**TIER II**

5.3      Specific toxicity, pathogenicity and infectiveness studies

5.4      Genotoxicity — *In vivo* studies in somatic cells

5.5      Genotoxicity — *In vivo* studies in germ cells

**END OF TIER II**

5.6      Summary of mammalian toxicity, pathogenicity and infectiveness and overall evaluation

**VI      RESIDUES IN OR ON TREATED MATERIALS, FOOD AND FEED**

6.1      Persistence and likelihood of multiplication in or on treated materials, feedingstuffs or foodstuffs

6.2      Further information required

6.2.1    Non-viable residues

6.2.2    Viable residues

6.3      Summary and evaluation of residues in or on treated materials, food and feed

**VII      FATE AND BEHAVIOUR IN THE ENVIRONMENT**

7.1      Persistence and multiplication

7.1.1    Soil

7.1.2    Water

7.1.3    Air

7.2      Mobility

7.3      Summary and evaluation of fate and behaviour in the environment

**VIII      EFFECTS ON NON-TARGET ORGANISMS**

8.1      Effects on birds

8.2      Effects on aquatic organisms

**First schedule      Part 8      Annex IVA      Data set for active substances**  
**Micro-organisms including viruses and fungi**

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- 8.2.1    Effects on fish
- 8.2.2    Effects on freshwater invertebrates
- 8.2.3    Effects on algae growth
- 8.2.4    Effects on plants other than algae
- 8.3      Effects on bees
- 8.4      Effects on arthropods other than bees
- 8.5      Effects on earthworms
- 8.6      Effects on soil micro-organisms
- 8.7      Further studies
- 8.7.1    Terrestrial plants
- 8.7.2    Mammals
- 8.7.3    Other relevant species and processes
- 8.8. Summary and evaluation of effects on non-target organisms

**IX      CLASSIFICATION AND LABELLING**

The dossier shall be accompanied by a reasoned proposals for allocating an active substance which is a micro-organism to one of the risk groups specified in Article 2 of Directive 2000/54/EC of the European Parliament and of the Council of 18 September 2000 on the protection of workers from risks related to exposure to biological agents at work (1) together with indications on the need for products to carry the biohazard sign specified in Annex II to that Directive.

**X      SUMMARY AND EVALUATION OF SECTIONS I TO IX INCLUDING CONCLUSIONS  
OF THE RISK ASSESSMENT AND RECOMMENDATIONS**

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## **SECOND SCHEDULE**

### **Part 9**

#### **Annex IVB**

#### **DATA SET FOR BIOCIDAL PRODUCTS**

#### **MICRO-ORGANISMS INCLUDING VIRUSES AND FUNGI**

- 1 For the purposes of this Annex, the term micro-organisms shall be understood as including also viruses and fungi. This Annex provides data requirements for the authorization of a biocidal product based on preparations of micro-organisms. For all biocidal products based on preparations containing micro-organisms that are subject to application, all available relevant knowledge and information in literature should be provided. The information related to the identification and characterization of all components in a biocidal product is particularly important and must be entered in sections I to IV and provides the basis for an assessment of possible impacts on human health and the environment.
- 2 Where, information is not necessary owing to the nature of the biocidal product the provisions of Regulation 4 (6) shall apply.
- 3 Information may be derived from existing data where a justification acceptable to the competent authority is provided. In particular, the provisions of Directive 67/548/EEC and Directive 1999/45/EC of the European Parliament and of the Council of 31 May 1999 concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations (1) shall be used wherever possible to minimise animal testing.
- 4 Where testing is done, a detailed description (specification) of the material used and its impurities, according to the provisions of Section II, must be provided. Where necessary, data as established in Annexes IIB, IIIB shall be required for all the toxicologically/ecotoxicologically relevant chemical components of the biocidal product, in particular if the components are substances of concern as defined in Regulation 2 (1).
- 5 In cases where a new preparation is to be dealt with, extrapolation from Annex IVA, could be acceptable, provided that all the possible effects of the components, especially on pathogenicity and infectiveness, are evaluated.

#### **Dossier requirements**

#### **SECTIONS:**

- I Identity of the biocidal product
- II Physical, chemical and technical properties of the biocidal product
- III Data on application

**Second schedule    Part 9    Annex IVB    Data set for biocidal product**  
**Micro-organisms including viruses and fungi**

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- IV      Further information on the biocidal product
- V       Analytical methods
- VI      Efficacy data
- VII     Effects on human health
- VIII    Residues in or on treated materials, food and feed
- IX      Fate and behaviour in the environment
- X       Effects on non-target organisms
- XI      Classification, packaging and labelling of the biocidal product
- XI      Summary and evaluation of sections I to XI including conclusions of the risk assessment and recommendations

The following data will be required to support submissions on the above points.

**I            IDENTITY OF THE BIOCIDAL PRODUCTS**

- 1.1      Applicant
- 1.2      Manufacturer of the biocidal product and the micro-organism(s)
- 1.3      Trade name or proposed trade name, and manufacturer's development code number of the biocidal product
- 1.4      Detailed quantitative and qualitative information on the composition of the biocidal product
- 1.5      Physical state and nature of the biocidal product
- 1.6      Function

**II           PHYSICAL, CHEMICAL AND TECHNICAL PROPERTIES OF THE BIOCIDAL PRODUCT**

- 2.1      Appearance (colour and odour)
- 2.2      Storage stability and shelf-life
  - 2.2.1    Effects of light, temperature and humidity on technical characteristics of the biocidal product
  - 2.2.2    Other factors affecting stability

**Second schedule    Part 9    Annex IVB    Data set for biocidal product**  
**Micro-organisms including viruses and fungi**

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- 2.3    Explosivity and oxidising properties
- 2.4    Flash point and other indications of flammability or spontaneous ignition
- 2.5    Acidity, alkalinity and pH value
- 2.6    Viscosity and surface tension
- 2.7    Technical characteristics of the biocidal product
  - 2.7.1    Wettability
  - 2.7.2    Persistent foaming
  - 2.7.3    Suspensibility and suspension stability
  - 2.7.4    Dry sieve test and wet sieve test
  - 2.7.5    Particle size distribution (dustable and wettable powders, granules), content of dust/fines (granules), attrition and friability (granules)
  - 2.7.6    Emulsifiability, re-emulsifiability, emulsion stability
  - 2.7.7    Flowability, pourability (rinsability) and dustability
- 2.8    Physical, chemical and biological compatibility with other products including biocidal products with which its use is to be authorized or registered
  - 2.8.1    Physical compatibility
  - 2.8.2    Chemical compatibility
  - 2.8.3    Biological compatibility
- 2.9    Summary and evaluation of physical, chemical and technical properties of the biocidal product
- 
- III    DATA ON APPLICATION
  - 3.1    Field of use envisaged
  - 3.2    Mode of action
  - 3.3    Details of intended use
  - 3.4    Application rate
  - 3.5    Content of micro-organism in material used (*e.g.* in the application device or bait)
  - 3.6    Method of application



**Second schedule    Part 9    Annex IVB    Data set for biocidal product**  
**Micro-organisms including viruses and fungi**

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- 3.7    Number and timing of applications and duration of protection
- 3.8    Necessary waiting periods or other precautions to avoid adverse effects to human and animal health and the environment
- 3.9    Proposed instructions for use
- 3.10    Category of users
- 3.11    Information on the possible occurrence of the development of resistance
- 3.12    Effects on the materials or products treated with the biocidal product

**IV    FURTHER INFORMATION ON THE BIOCIDAL PRODUCT**

- 4.1    Packaging and compatibility of the biocidal product with proposed packaging materials
- 4.2    Procedures for cleaning application equipment
- 4.3    Re-entry periods, necessary waiting periods or other precautions to protect man, livestock and the environment
- 4.4    Recommended methods and precautions concerning: handling, storage, transport or fire
- 4.5    Measures in the case of an accident
- 4.6    Procedures for destruction or decontamination of the biocidal product and its packaging
  - 4.6.1    Controlled incineration
  - 4.6.2    Others
- 4.7    Monitoring plan to be used for the active micro-organism and other micro-organism(s) contained in the biocidal product including handling, storage, transport and use

**V    ANALYTICAL METHODS**

- 5.1    Methods for the analysis of the biocidal product
- 5.2    Methods to determine and quantify residues

**VI    EFFICACY DATA**

**VII    EFFECTS ON HUMAN HEALTH**

**Second schedule    Part 9    Annex IVB    Data set for biocidal product  
Micro-organisms including viruses and fungi**

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7.1    Basic acute toxicity studies

7.1.1    Acute oral toxicity

7.1.2    Acute inhalation toxicity

7.1.3    Acute percutaneous toxicity

7.2    Additional acute toxicity studies

7.2.1    Skin irritation

7.2.2    Eye irritation

7.2.3    Skin sensitisation

7.3    Data on exposure

7.4    Available toxicological data relating to non-active substances

7.5    Supplementary studies for combinations of biocidal products

7.6    Summary and evaluation of effects on human health

VIII    RESIDUES IN OR ON TREATED MATERIALS, FOOD AND FEED

IX    FATE AND BEHAVIOUR IN THE ENVIRONMENT

X    EFFECTS ON NON-TARGET ORGANISMS

10.1    Effects on birds

10.2    Effects on aquatic organisms

10.3    Effects on bees

10.4    Effects on arthropods other than bees

10.5    Effects on earthworms

10.6    Effects on soil micro-organisms

10.7    Additional studies on additional species or higher tier studies such as studies on selected non-target organisms

10.7.1    Terrestrial plants

**Second schedule    Part 9    Annex IVB    Data set for biocidal product**  
**Micro-organisms including viruses and fungi**

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10.7.2 Mammals

10.7.3 Other relevant species and processes

10.8 Summary and evaluation of effects on non-target organisms

**XI CLASSIFICATION, PACKAGING AND LABELLING OF THE BIOCIDAL PRODUCT**

As established in accordance with the provisions of Regulation 30, proposals including justification for the classification and labelling of the biocidal product in accordance with the provisions set in Directive 67/548/EEC and Directive 1999/45/EC must be submitted. The classification comprises of the description of the category/categories of danger and qualifying risk phrases for all dangerous properties. On the basis of the classification, a proposal for labelling including the hazard symbol(s) and indications of danger, risk phrases and safety phrases should be given. The classification and labelling shall be in regard to the chemical substances contained in the biocidal product. If necessary, specimens of proposed packaging shall be submitted to the competent authority of a Member State.

The dossier shall be accompanied by a reasoned proposal for allocation to one of the risk groups specified in Article 2 of Directive 2000/54/EC together with indications on the need for products to carry the biohazard sign specified in Annex II to that Directive.

**XII SUMMARY AND EVALUATION OF SECTIONS I TO XI INCLUDING CONCLUSIONS OF THE RISK ASSESSMENT AND RECOMMENDATIONS'**

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**GIVEN** under my Official Seal ,

19<sup>th</sup> July 2006

L.S.

Mary Coughlan

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Minister for Agriculture and Food

Explanatory Note

(This note is not part of the instrument and does not purport to be a legal interpretation)

These Regulations amend the European Communities (Authorization, Placing on the Market, Use and Control of Biocidal Products) Regulations, 2001 (S.I. No. 625 of 2001) and give effect to Commission Directive 2006/50/EC of 29 May 2006 amending Annex IVA and IVB of the European Parliament and of the Council concerning the placing of biocidal products on the market.

The amendments specify requirements concerning the maintenance of records of use of biocidal products by end-users and amend the data requirements for active substances and biocidal products that are micro-organisms, including viruses and fungi. These Regulations also serve to define certain terms and to update the enforcement provisions of the Regulations.